

Appl. No. 10/080,920  
Amdt. dated January 25, 2006  
Amendment under 37 CFR 1.116 Expedited Procedure  
Examining Group 3731

PATENT

### REMARKS/ARGUMENTS

A Request for Continued Examination was filed on September 8, 2005 in response to an Advisory Action of June 23, 2005 which noted that the proposed amendment would not be entered because it raised new issues that would require further search and/or consideration. A Final Office Action issued rejecting the pending claims. Claims 1, 2, 46, 47, 100, and 107 have been further amended to more clearly claim the present invention. Claim 91 has been canceled. Re-examination and reconsideration of pending claims 1, 2, 11-18, 20-23, 26-28, 31, 32, 35, 45-49, 69, 71, 73, 74, 76, 79-85, 97-101, and 107, as amended, are respectfully requested. Applicants request at a minimum that the finality of the present Office Action be removed and that the present amendment be entered.

#### Examiner Interview

Applicants thank Examiner Webb for the kind and courteous interview on November 18, 2005. Independent claims 1 and 2 were discussed in light of the 35 U.S.C. § 112 rejection and the 35 U.S.C. § 103 rejection. It was agreed that Applicants' proposed amendments to more clearly define the balloon sleeve and sleeve passage overcome the 35 U.S.C. § 112 rejection.

#### 35 U.S.C. § 112 Rejection

Claims 1, 2, 11-18, 20-23, 26-28, 31, 32, 35, 45-49, 69, 71, 73, 74, 76, 79-85, 97-101, and 107 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1, 2, 46, 47, 100, and 107 have been amended to more clearly define the balloon sleeve and sleeve passage. Support for these amendments can be found throughout the originally filed disclosure, including Fig. 5A and paragraphs 73-76. As such, Applicants request the removal of this rejection.

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35 U.S.C. §103 Rejection

Claims 1, 2, 11, 12, 16-18, 22-23, 26-28, 35, 46-49, 69, 73, 76, 79-85, 97-101, and 107 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,655,746 issued to Daniels et al. in view of U.S. Patent No. 5,135,535 issued to Kramer. Such a rejection is traversed in part and overcome in part as follows.

Independent claims 1 and 2 have been amended to expedite prosecution of the present case and more clearly claim the present invention. Claim 1 now recites an intravascular balloon catheter (10") comprising a catheter body (12) and a first balloon structure (14). The catheter body (12) has a proximal end, a distal end, and a guidewire lumen (20) therebetween. The first balloon structure (14) has a shaft (26), a balloon sleeve (38), and a sleeve passage (41) which is slidably receivable over the catheter body (12) and disposed over the shaft (26), and an axial groove (102) along at least a portion of the structure (26) and the passage (41) to removably receive at least a portion of the catheter body (12). Claim 2 has been similarly amended.

The present rejection does not establish *prima facie* obviousness under 35 U.S.C. § 103 and M.P.E.P. §§ 2142-2143. In the instant case, the prior art references, alone or in combination, fail to teach or suggest all the claim limitations. M.P.E.P. §2143.03; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974). In particular, the distinctly claimed ***axial groove that extends along at least a portion of the sleeve passage*** has not been shown or suggested in any of the cited art references, alone or in combination.

The Daniels et al. reference is directed at a catheter device as shown in Figure 3. Significantly, this reference fails to remotely teach or suggest any axial groove elements as required by claims 1 and 2. The Examiner further appears to agree that "Daniels fails to form the balloon structure shaft (16) to have an axial groove." Office Action, page 3. The Examiner then attempts to cure this deficiency with the Kramer reference by maintaining that:

Kramer discloses another balloon catheter that includes a first balloon structure shaft (11) that has a passage (14) that receives a guidewire (29). Kramer teaches that the shaft (11) should include an **axial slit (23, 24), or groove, along the length of the shaft proximal to the balloon**. The groove (23, 24) allows the balloon structure shaft (11, 13) to be removed from the guidewire (29) while the guidewire (29) remains stationary in the body lumen. A replacement catheter

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may then be subsequently delivered over the guidewire (see column 6, lines 22-48).

*Id.*

Although the Kramer catheter (10) may have slits (23, 24) that allow for separation of the guidewire (29) from the guidewire lumen (14) of the catheter (10), it is important to note (as the Examiner has above in the bolded section) that the slit (24) ends at "**a location proximal to the proximal end 25 of balloon 13.**" See col. 5, lines 25-32. As such, these slits described by Kramer fail to define an axial groove that extends along at least a portion of the sleeve passage, the passage being slidably receivable over the catheter body and disposed over the balloon structure shaft. It is further Applicants position that there is no motivation to modify Kramer so that its slit (24) extends beyond the proximal end of the balloon as that would prevent inflation of the balloon member. In contrast, the present invention allows for the axial groove (102) to extend along at least a portion of the sleeve passage (41) as the balloon sleeve (38) forms a part of the inflation lumen within the balloon (40) as noted in paragraph 73 of the present application.

Further, the Examiner mentions that, "the references cited, such as Kramer and Schiffer, include teachings pertaining to the axial groove." Office Action, pages 6-7. With respect to Schiffer, Figures. 1-3 illustrate a catheter (10) having a breakaway feature or tear strip (32) that allows for separation of the guidewire (18) from the guidewire lumen (30) of the catheter. At best, Schiffer teaches that the guidewire lumen may be opened along the tear strip. This reference similarly fails to teach or suggest the distinct structural limitation of an axial groove that extends along at least a portion of the sleeve passage, wherein the passage is defined by being slidably receivable over the catheter body and disposed over the balloon structure shaft. Applicants request, if the present rejection is maintained, that the Examiner show or explain where the Kramer, Schiffer, and/or any other reference of record teaches or suggest the distinct structural limitation of claims 1 and 2, particularly an axial groove (102) that extends along at least a portion of the sleeve passage (41). Absent such a showing, Applicants request the withdrawal of these rejections and allowance of independent claims 1 and 2 (and the claims which depend therefrom.)

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**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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